

**STATE OF MICHIGAN**  
**DEPARTMENT OF LABOR & ECONOMIC GROWTH**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

In the matter of

XXXXX

Petitioner

File No. 90105-001

v

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 14<sup>th</sup> day of August 2008  
by Ken Ross  
Commissioner

**ORDER**

**I**  
**PROCEDURAL BACKGROUND**

On June 2, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on June 9, 2008.

Because it involved medical issues the Commissioner assigned the case to an independent review organization (IRO) which provided its analysis and recommendations to the Commissioner on June 18, 2008.

**II**  
**FACTUAL BACKGROUND**

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) through the Michigan Education Special Services Association (MESSA), an underwritten group. Coverage is governed by MESSA's *Choices II Group Insurance for School Employees* certificate of coverage (the certificate).

The Petitioner suffers from allergies. She has been a patient at XXXXX for several years. The Petitioner was prescribed sublingual drops and XXXXX billed the drops under procedure code 95199 (unlisted allergy service or procedure). According to BCBSM, several of the claims were paid in error and others were rejected. BCBSM has agreed not to attempt to recall the \$253.00 in payments it believes were made in error. At issue in this appeal are August 10, 2007 and November 5, 2007 prescriptions. Allergy Associates charged \$87.00 for each prescription. BCBSM denied coverage.

The Petitioner appealed BCBSM's denial of the unpaid claims. After a managerial-level conference on April 2, 2008, BCBSM did not change its decision and issued a final adverse determination dated May 14, 2008.

### **III ISSUE**

Did BCBSM properly deny payment for the Petitioner's sublingual medication?

### **IV ANALYSIS**

#### **Petitioner's Argument**

BCBSM refuses to pay for sublingual immunotherapy antigens even though they pay for the exact same material when it is delivered by injection. Their stance is that it is experimental. The Petitioner believes that 40 years of experience and studies showing it to be effective, and the Petitioner's own successful experience, prove that sublingual application of antigens is more effective than shots. Therefore, the Petitioner believes that this service is not experimental and should be a covered benefit under the certificate.

#### **BCBSM's Argument**

BCBSM believes the sublingual antigen drops provided to the Petitioner are experimental or investigational and therefore not a covered benefit. It points to this exclusion in "Section 10: Exclusions and Limitations" of the certificate (page 49):

- services and supplies that are not medically necessary according to accepted standards of medical practice including any services which are experimental or investigational

The certificate (on page 4) defines the term “experimental or investigational” as “[a] service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient’s condition as conventional or standard treatment.” BCBSM’s medical consultants reviewed the medical documentation and determined that the use of sublingual antigen drops is investigational because it has not been proven to be clinically effective.

BCBSM recognizes that some of the Petitioner’s claims did get paid in error. This does not change the fact that sublingual antigen drops are not a covered benefit and BCBSM is not required to pay for them.

#### Commissioner’s Review

The certificate sets forth the benefits that are covered. A procedure that is not accepted as the standard of care and has not been demonstrated to be as safe or effective as conventional or standard treatment is considered to be experimental or investigational and is not a benefit under the terms of the Petitioner’s coverage.

The question of whether the Petitioner’s sublingual antigen drops are experimental or investigational for treatment of her condition was presented to an IRO for analysis as required by section 11(6) of PRIRA. The IRO physician reviewer is certified by the American Board of Internal Medicine and the American Board of Allergy and Immunology. The reviewer is a member of the American Academy of Allergy, Asthma and Immunology and is published in peer-reviewed medical literature.

The IRO report states:

This is a case where the enrollee was placed on sublingual immunotherapy (SLIT). Although European studies have shown the efficacy of SLIT, this treatment has not yet been approved in the United States (U.S.). As a result, until treatment with sublingual allergen drops is approved by the Food and Drug Administration . . . it

would still be considered experimental/investigational at this time.

\* \* \*

Some studies are underway; however, per this reviewer's literature search, there is no peer reviewed medical literature regarding any research studies in the U. S. concluding that SLIT should be considered a viable treatment option and/or considered the standard of care.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the conclusion of the IRO that the Petitioner's sublingual antigen drops are experimental and/or investigational and finds that they are therefore not covered under the terms of the Petitioner's certificate.

## **V ORDER**

Respondent BCBSM's May 14, 2008, final adverse determination is upheld. BCBSM is not required to cover the Petitioner's sublingual antigen drops since they are considered to be investigational for treatment of her condition.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.